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THERAPEUTIC MEDICAL APPLIANCE, DELIVERY AND METHOD OF USE

FIELD OF INVENTION

The present invention relates generally to medical devices directed to interventional treatment, and more particularly to plugs,
5 delivery devices and methods for utilizing these plugs in the treatment of pulmonary disorders such as defects characterized by pulmonary blebs and/or diffused destructive parenchymal disease.

BACKGROUND OF THE INVENTION

Therapeutic medical appliances are devices that are inserted
10 into a vessel or passage to keep the lumen open and prevent closure due to a stricture, external compression, or internal obstruction. In particular, therapeutic medical appliances are commonly used to keep blood vessels open in the coronary arteries and they are frequently inserted into the ureters to maintain drainage from the
15 kidneys, the bile duct for pancreatic cancer or cholangiocarcinoma or the esophagus for strictures or cancer. Vascular as well as not vascular therapeutic medical applianceing has evolved significantly; unfortunately there remain significant limitations with respect to the technology for producing therapeutic medical appliances suitable to
20 various portions of a patient's anatomy.

Unfortunately, because of the topology of the human lungs generally and the various lobes in particular, traditional therapeutic medical applianceing is not effective in the treatment of pulmonary blebs and/or diffused destructive parenchymal disease. In most
25 cases, attempts are made to section off lung tissue, which generally

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results in fluid retention and concomitant complications. Even if there was a way to delivery a therapeutic medical appliance to one bleb, it would require multiple procedures to address the common presence of multiple blebs.

5 Physicians have attempted to improve lung function in patients with emphysema by utilizing lung volume reduction procedures. The principal behind such procedures is that if the increased residual volume created by the bullous of disease could be reduced, the patients' respiratory limitations could be alleviated. Lung volume
10 reduction procedures are very invasive and are only available to a minority of emphysema patients and require significant post surgical care and rehabilitation. Alternative systems have attempted to install valve systems that allow for the alleviation of respiratory limitations by closing blebs without the undesirable back filling of the
15 closed areas. Regrettably, the valve system has a relatively short useful life, and therefore limited applicability, since patients with emphysema also have chronic bronchitis and thus lots of secretions in their airways to obstruct the valves. Moreover, placement of these valves requires invasive procedures as well.

20 Therefore there remains a need for a therapeutic medical appliance that can be placed in the segmental airways so as to reduce the residual volume and improve ventilation in a less invasive manner. Chiefly, there remains an existing need for a device and delivery method for installing the device in the lungs of a patient to
25 treat pulmonary blebs or other suitable abnormalities. In particular, there is a need for a specialized therapeutic medical appliance designed to plug fissures or other abnormal anatomical openings. Moreover, there is an existing need for an interventional technique that allows for the delivery of multiple therapeutic medical

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appliances during a single procedure, without having to remove the delivery device. A need also remains for a delivery device that can be reloaded with a plurality of therapeutic medical appliances. There also remains a need for a method of treating pulmonary blebs that
5 prevents disease recurrence in, aggravation and/or deterioration of the patient's pulmonary health.

SUMMARY OF EXEMPLARY EMBODIMENTS

It is a principal purpose of the present invention to provide a specialized medical appliance, in accordance with an exemplary
10 embodiment of the present invention, which can be indicated for a number of disorders, including particularly the treatment of pulmonary disorders such as defects characterized diffused destructive parenchymal disease. In particular, it is an objective of a preferred embodiment in accordance with the present invention to provide a
15 medical appliance that is easily installed, yet in alternative embodiments, removable. Moreover the medical appliance in accordance with this embodiment of the present invention would not cause material infections and may be capable of reducing infection. Therefore, a principal objective of a preferred embodiment in
20 accordance with the present invention is to provide a prosthesis that is suitable for both permanent and temporary use while being easy to insert, reposition and remove.

A principal objective of a preferred embodiment of the present invention is to provide a medical appliance that may be stamped
25 from preferably a single material that is capable of maintaining its axial working length when radially compressed. To this end, the therapeutic medical appliance does not have a seam that could aggravate luminal tissue. In particular, a medical appliance in

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accordance with the present invention is formed using a tool that molds the medical appliance's outer contour as well as its interstices.

It is yet another objective of an exemplary embodiment of the present invention to provide a medical appliance that can be
5 indicated for the treatment of pulmonary blebs and improve the way clinicians treat malignant obstructions.

Still another objective of the present invention is to provide a medical appliance and method for installing the medical appliance that is economical and suitable for routine purposes. Moreover, a
10 preferred embodiment of the medical appliance has a self-sealing membrane at one or both end to allow for the closing off of the target area while allowing the physician to introduce and/or evacuate material there through.

A principal objective of an exemplary therapeutic medical
15 appliance in accordance with the present invention is to provide a family of medical appliances where the relative hardness/softness of regions of the therapeutic medical appliance can differ from other regions of the therapeutic medical appliance to provide additional patient comfort and resistance to radial forces.

20 An additional objective in accordance with an exemplary embodiment is to provide a family of medical appliances with novel interstice configurations that facilitate flexibility, durability and/or proper installation.

Yet another principal objective of an exemplary delivery system
25 in accordance with the present invention to provide a device that can facilitate the precise delivery of the medical appliances in a safe and repeatable fashion. In the furtherance of this and other objectives, a preferred deployment apparatus allows the physician to concentrate on correct placement without having to estimate

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extent of deployment. In particular, in a preferred embodiment, the present device has a physical safety mechanism that limits deployment to the critical deployment point (i.e., ~60%). The critical deployment point may range from 5% to 95% but is preferably about 5 60%. At this point, if the physician is satisfied with placement, she can engage the safety means to what we refer to as the Proceed Orientation (PO) and fully deploy the medical appliance. It is preferred that when the safety mechanism is engaged to the PO, a tactile, visual and/or possible audible indicator sounds to inform the 10 physician that if she deploys the therapeutic medical appliance any further, she can no longer retract the therapeutic medical appliance beyond this point. Though the present therapeutic medical appliance and delivery system eliminates the need for repositioning, such safety features are still preferable. In a preferred embodiment, the slight 15 audible indication is the sound of a tab or stop snapping to allow free deployment of the therapeutic medical appliance.

Still another objective of an exemplary embodiment in accordance with the present invention is to provide a delivery system that allows for the placement of multiple medical appliances during a 20 single procedure without having to first remove the delivery device. Moreover, the delivery device in alternative embodiments may be reloaded by attaching removable medical appliance containing housings thereto.

An additional objective in accordance with an alternative 25 embodiment of the present invention is to provide a delivery system that has an outer tubular member of sufficient cross sectional thickness to define a plurality of longitudinally extending channels for receiving additional utility tools. In the furtherance of this and other objectives, and by way of example only, one such channel could

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accommodate an ultra thin scope while an alternative channel receives a guidewire, syringe systems, etc. Principally, these channels are suitable for receiving a number of other tools that a physician may need during deployment of a therapeutic medical appliance or
5 therapeutic treatment of target tissue.

Still another objective in accordance with a preferred embodiment of the present invention is to provide a device having direct visualization capabilities directly incorporated into the device.

In addition to the above objectives, an exemplary deployment
10 system preferably has one or more of the following characteristics: (1) biocompatible; (2) compliant with specialized radially expanding plug medical appliances; (3) capable of distal or proximal medical appliance release; (4) smooth and clean outer surface; (5) length of the device variable according to the insertion procedure to be
15 employed; (6) outer dimension as small as possible (depends on the diameter of crimped medical appliance); (7) dimensions of the device must offer enough space for the crimped medical appliance; (8) sufficient flexibility to adapt to anatomical curvatures without loss of ability to push or pull; (9) low friction between the moving parts;
20 (10) sufficient resistance to kinking; (11) good deployment force, ability to reposition partially deployed medical appliance; and (12) sufficiently economical to manufacture so as to make the deployment apparatus disposable.

Further objectives, features and advantages of the invention
25 will be apparent from the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

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FIG. 1 is a perspective view of the outer tube that constrains the therapeutic medical appliance by radial compression, the tube shown with grooves for receiving the tracks that permit the device to contain a plurality of therapeutic medical appliance while only
5 allowing one stent to be deployed at a time;

FIG. 2 shows the tracks that ride in the grooves of the outer sheath of FIG. 1, wherein the grooves preferably have unidirectional members that permits the device to deploy a single therapeutic medical appliance and reload multiple times within one procedure;

10 FIG. 3 shows a plurality of therapeutic medical appliances and the relative location of at least two tracks with respect to the therapeutic medical appliances;

FIG. 4 shows an embodiment of a reloadable delivery device where the therapeutic medical appliance-containing tip snaps onto
15 the outer tube and/or the inner to form the distal region of the delivery device.

FIG. 5 shows an alternative embodiment of the reloadable delivery device of FIG. 4 where the therapeutic medical appliance-containing tip snaps onto the outer tube and/or the inner to form the
20 distal region of the delivery device.

FIG. 6 shows an alternative embodiment of a reloadable delivery device where the therapeutic medical appliance-containing tip has a friction fit coupling with the outer tube and/or the inner to form the distal region of the delivery device.

25 FIG. 7 shows an alternative embodiment of a reloadable delivery device showing the threading components of the reloadable tip.

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FIG. 8 provides perspective views of the therapeutic medical appliance that does not have a self-sealing membrane at the distal tip.

DETAILED DESCRIPTION OF AN EMBODIMENT

5 The present invention, in a preferred embodiment, provides a therapeutic medical appliance, the delivery system, and method of using the appliance and delivery system for the treatment of abnormalities, defined by fissures or other openings in the tissue, that require the closing or sealing off of the abnormalities. In particular,
10 the present medical appliance is designed to treat pulmonary blebs and/or diffused destructive parenchymal disease in a patient. To this end, preferred delivery systems allow the user to install the multiple therapeutic medical appliances in various target sites in the segmental airway during a single procedure. In alternative
15 embodiments, the delivery system may be reloadable with one or more additional therapeutic medical appliances.

A preferred therapeutic medical appliance is preferably formed from a composite material selected from the group consisting essentially of Ni, C, Co, Cu, Cr, H, Fe, Nb, O, Ti, plastic, other polymers in
20 general and bioabsorbable polymers, in particular, and combinations thereof. However, alternative materials such as polymeric material, is acceptable provided that the therapeutic medical appliance has radial self-expansion ability. Making specific reference to the memory metal embodiments, the composite material is generally formed into
25 a compressed tube from which the therapeutic medical appliance is etched and is formed on a suitable shaping device to give the therapeutic medical appliance the desired external geometry. Both the synthetic collar techniques and in vitro valuation techniques show the remarkable ability of therapeutic medical appliances in

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accordance with the present invention to convert acting force into deformation work absorbed by the angled structure, which prevents excessive scaffolding stress and premature material fatigue and accelerated obsolescence.

5 Though one skilled in the therapeutic medical appliance engineering art, once apprised of the present application, would be able to manufacture a therapeutic medical appliance consistent with the present invention by other methods, a preferred method of manufacturing such therapeutic medical appliances follows. As
10 stated above a composite material is selected and a blank is formed there from. The blank is preferably laser etched and the etch work is generally verified for accuracy using visual recording microscopy. Dimensional measurements are taken to ensure strut thickness, segment angles, zone placement, etc. Moreover, the therapeutic
15 medical appliance is preferably formed on a shaping tool that has substantially the desired contour of the external therapeutic medical appliance dimensions.

 In the event the therapeutic medical appliance is to be shaped to the dimensions of a particular lumen, optical photography and/or
20 optical videography of the target lumen may be conducted prior to therapeutic medical appliance formation. Alternatively, a appliance sizing device like the Lumenaide™ designed by Alveolus Inc may be used. The geometry of corresponding zones and connector regions of the therapeutic medical appliance then can be etched and formed
25 in accordance with the requirements of that target lumen.

 It should be pointed out that unlike the use of differing shape memory materials to change regions of a therapeutic medical appliance, therapeutic medical appliances in accordance with the present invention can take on an infinite number of characteristic

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combinations as zones and segments within a zone can be modified by changing angles, segment lengths and segment thicknesses during the etching and forming stages of therapeutic medical appliance engineering or during post formation processing and polishing steps.

- 5 Moreover, by modifying the geometry of the connectors between zones, additional functionality may be achieved.

Exemplary therapeutic medical appliances in accordance with the present invention may be manufactured for particular lumen in accordance with the manufacturing procedures and containing the
10 characteristics of the devices disclosed in Patent Application Serial No. 10,288,615, which has been incorporated in its entirety by this reference.

The therapeutic medical appliance is preferably formed of memory metal and preferably has unique geometrical interstices that
15 are laser etched therein. However, other conventional ways of forming interstices in unitary therapeutic medical appliances, though not equivalent are contemplated and may be employed and would be within the skill set of one in the art.

It cannot be overemphasized, however, that this does not
20 mean the knowledge that changes in the geometry of interstices affect therapeutic medical appliance functionality is currently known in the art. To the contrary, the present inventors discovered the interrelation between interstice geometry, width, length and relative resistance to torsional stress and radial force. In fact, it can be said
25 that the therapeutic medical appliance has circumferential bands extending perpendicularly with respect to the luminal device's longitudinal axis. These bands are referred to generally as zones. A connector connects these bands to one another; the connector is an additional means for adjusting therapeutic medical appliance

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functionality. In particular, the connector defines a substantially U shaped member, but could define other geometries such as U, V, W, Z, S and X to name a few.

With specific reference being made to a preferred
5 embodiment of the present invention, a therapeutic medical
appliance is provided for introduction into a cavity in the anatomy of
a patient, the medical appliance comprising a tube with first and
second ends and the tube defining a cavity extending between the
first and second ends, the medical appliance further comprising a self-
10 sealing membrane coupled about the first end thereof. Preferred self-
sealing membrane materials include but are not limited to polymers
such as thin rubber.

In the instance where the target location of the therapeutic
medical appliance(s) is the lungs, multiple appliances may be needed
15 in order to treat the patient. Unfortunately, heretofore there was no
appliance suitable for such treatment, nor was there a device that
allows the installation of multiple appliances during a single
moderately invasive procedure. A preferred device comprises a
longitudinally extending outer tubular member having distal and
20 proximal ends and an interior and exterior surface, the outer tubular
member defines a lumen longitudinally extending substantially the
distance from the distal end to the proximal end of the outer tubular
member and forming a longitudinal expanse there between, running
parallel to the longitudinal expanse are a plurality of grooves, the
25 longitudinal expanse forming a lumen there through; a plurality of
tracks complementary and slidably coupled with the grooves such
that the tracks and the grooves linearly displaceable with respect to
the other, the tracks having proximal and distal ends and a plurality of
tabs spaced at a functional distance apart from one another

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between the proximal and distal ends thereof, the tabs facing toward the lumen of the outer tubular member; and a handle, coupled with a portion of the outer tubular member, the handle having first and second ends. The handle cooperates with the tracks in a manner

5 consistent with reliable and deliberate delivery of each therapeutic medical appliance. In alternative embodiments, the delivery device comprises a safety system like the one provided in U.S. Patent Application Serial No. 10/404,197, which is incorporated in its entirety by this reference. With respect to the safety mechanism, a preferred

10 mechanism is a physical safety mechanism that limits deployment to the critical deployment point (i.e., ~60%). The critical deployment point may range from 5% to 95% but is preferably about 60% or a proportional stop relative to the stent length. At this point, if the physician is satisfied with placement, she can engage the safety

15 means to what we refer to as the Proceed Orientation (PO) and fully deploy the therapeutic medical appliance. It is preferred that when the safety mechanism is engaged to the PO, a sensation or possible audible indicator sounds to inform the physician that if she deploys the therapeutic medical appliance any further, she can no longer retract

20 the delivery system beyond this point and still reposition the therapeutic medical appliance. Certain embodiments (not shown) provide for re-constraint beyond this point. In addition to or as an alternative, the tabs on the tracks also serve as a safety function to prevent deployment of more than one appliance at a time while

25 also facilitating reloading. Though the present stent and delivery system eliminates the need for repositioning, such safety features are still preferable. In a preferred embodiment, the slight audible indication is the sound of a tab or stop snapping or being traversed to

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allow free deployment of the appliance. The therapeutic medical appliance may also have seating barbs for retention.

The distal end of the device may be configured such that a portion of the distal region is removable, preferably including the distal portions of the tracks such that a housing containing additional therapeutic medical appliances can be coupled with the device to form a reloadable delivery device. Alternatively, the device may be reloaded with a single appliance containing distal tip, which can be screwed onto the device or coupled with the device by other conventional means.

Making specific reference to the FIGS, a therapeutic medical appliance and delivery device are provided in various embodiments.

Referring generally to the figures where like numerals refer to like parts, varying embodiments of a reusable delivery system, a multifire delivery system and a therapeutic medical appliance are shown. Specifically, referring to FIG. 1, the outer tubular member 200 (alternatively known as an outer sheath) is provided with recesses 220 (alternatively known as grooves) for operatively receiving tracks 300 therein. The outer sheath 200 in certain embodiments can participate in the constraining of the therapeutic medical appliance 100. This is particularly relevant in cases where the therapeutic medical appliance 100 comprises a memory alloy. The outer sheath 200 has both an interior surface 210 and an exterior surface 280, wherein the groove 220 is formed in the inner surface 210 of the outer sheath 200 and runs longitudinally along a portion thereof.

As shown in FIG. 2, track 300 is operably coupled with groove 220 so as to be slideable therein. The track 300 has a distal end 320, first and second sides 330 and 360. Track 300 also has a top surface 310 that is adjacent groove 220 when in an operable configuration. In

certain embodiments, first side 330 and/or second side 360 are in operable communication with groove 220 as well. Moreover, track 300 in preferred embodiments is configured with extensions 340 that preferably have unidirectional faces 350 that are adjacent the proximal region 130 of the therapeutic medical appliance 100 so as to assist with deployment of the therapeutic medical appliance 100 distally without allowing it to move proximally with respect to other therapeutic medical appliances. In preferred embodiments, multiple unidirectional surface containing members 340 are provided to allow for the housing of multiple therapeutic medical appliances 100 in the outer sheath 200. The outer sheath 200 may be configured to have one or more grooves 220 so as to receive one or more tracks 300. As shown in FIG. 3, the therapeutic medical appliance 100 is housed in between the outer sheath 200 directly or indirectly in the event that multiple tracks 300 are provided.

FIGS. 4-7 shows an alternative embodiment of a delivery system in accordance with preferred embodiments of the present invention wherein the system is reusable. In particular, an outer sheath 500 is provided that can be separated at junction 510. Junction 510 may comprise a coupling mechanism such as a snap, tension, screw or alternative mating. Shown in more detail in FIGS. 5 & 7 the distal end of the device may be separated from the proximal section. The distal region preferably comprises the section distal the proximal end of the stent, though the distal region may comprise more or less of the outer sheath 500. In embodiments that have an inner sheath 400, the inner sheath may also be removed at a junction similar to that found in the outer sheath 400. In such embodiments the region from the distal tip 410 to a predetermined point on the inner sheath 400 may be removed. The coupling of both the inner and the outer sheath can be

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accomplished by a variety of coupling means such as those listed above or that may be customary in the fastening art, even though they may not be obvious to use in medical devices prior to exposure to this disclosure.

5 Referring now to FIG. 8, a preferred therapeutic medical appliance 100 provides a device having a distal end, 110, a medial region 120 and a proximal end 130. Moreover, in certain embodiments, a self-healing membrane 150 is provided that allows for the penetration thereof without permanently damaging the
10 membrane 150. It is also envisioned in certain embodiments that the therapeutic medical appliance may be configured from a bioabsorbable material compatible with mammalian tissue such as a polyglycol.

It should be kept in mind that the handle may be coupled with a
15 portion of the outer sheath or other portions of the delivery system such as the tracks, inner sheath, etc. Moreover, in the reusable embodiments, the distal portion may be disposable or reloadable for reuse provided both the distal and the proximal portions of the device are sterilized before subsequent use.

20 In practice the therapeutic medical appliance and delivery device may be used to treat various defects, including but not limited to defects characterized by pulmonary blebs and/or diffused destructive parenchymal disease in a patient, by providing one or more therapeutic medical appliances and placing them about a
25 target site in a lung of a patient generally and the segmental airway in particular. Either independently or through utility channels in the outer tube of the delivery device, an adhesive can be introduced by a syringe into the lung through the self-sealing membrane of the therapeutic medical appliance. An adhesive, which is preferably a

localized inflammatory response causing and gas-absorbing agent, causes surfaces of lung sections to coalesce and seal the defect. Subsequently, the lung sections are collapsed by evacuating the inflammatory response causing and gas-absorbing agent.

- 5 The therapeutic medical appliance may be a simple formed of a any number of materials, including but not limited to a shape memory alloy, polymer, elastimer, etc. The self-sealing membrane is not required.

- 10 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes, which come within the meaning
15 and range of equivalency of the claims, are to be embraced within their scope.